



# Attorney Docket No. A041 CON

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner

Not Yet Assigned

Group Art Unit

1632

**Applicant** 

Jeffrey Browning

Application No.

10/696,259

Confirmation No.

7052

Filed

October 28, 2003

For

BMOG, A NOVEL PROTEIN MEMBER OF THE

MYELIN-OLIGODENDROCYTE GLYCOPROTEIN

FAMILY AND ITS USE FOR

IMMUNOMODULATORY PURPOSES

New York, New York September 30, 2004

### Mail Stop Amendment

Hon. Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

# INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicant, through his attorneys, makes of record the following documents, copies of which are enclosed herewith<sup>1</sup>:

# **UNITED STATES PATENTS**

<u>Patentee</u> <u>Patent No.</u>	Issue Date
Cabilly et al. 4,816,567	March 28, 1989
Hogan et al. 5,176,996	January 5, 1993
Froehler 5,256,775	October 26, 1993
Matteucci 5,264,564	November 23, 1993

<sup>&</sup>lt;sup>1</sup> A completed Form PTO-1449, listing these documents, is attached hereto.

### FOREIGN PATENTS/APPLICATIONS

Publication No.	Publication Date
WO 95/06727	03/09/95
EP 0412762 A2	02/13/91
EP 0750039 A1	12/27/96
EP 0031080 B1	07/01/81

#### **OTHER DOCUMENTS**

Adelman et al., "In Vitro Deletional Mutagenesis for Bacterial Production of the 20,000-Dalton Form of Human Pituitary Growth Hormone," <u>DNA</u>, 2: 183 (1983).

Arulanandam et al., "A Soluble Multimeric Recombinant CD2 Protein Identifies CD48 as a Low Affinity Ligand for Human CD2: Divergence of CD2 Ligands during the Evolution of Humans and Mice," J Exp Med, 177: 1439-1450 (1993).

Berkner et al., "Expression of Heterologous Sequences in Adenoviral Vectors," <u>Curr</u> Top Microbiol Immunol, 158: 39-61 (1992).

Bandyopadhyay et al., "Expression of Complete Chicken Thymidine Kinase Gene Inserted in a Retrovirus Vector," Mol Cell Biol, 4: 749-754 (1984).

Browning et al., "Preparation and Characterization of Soluble Recombinant Heterotrimeric Complexes of Human Lymphotoxins  $\alpha$  and  $\beta$ ," <u>J Biol Chem</u>, 271: 8618-8626 (1996).

Browning et al., "Characterization of Lymphotoxin- $\alpha\beta$  Complexes on the Surface of Mouse Lymphocytes," <u>J Immunol</u>, 159: 3288 (1997).

Burger, "Human Myelin/Oligodendrocyte Glycoprotein: A New Member or the L2HNK-1 Family," <u>J Neurochem</u>, 61, 1822-1827 (1993).

Chicheportiche et al., "TWEAK, a New Secreted Ligand in the Tumor Necrosis Factor Family that Weakly Induces Apoptosis," <u>J Biol Chem</u>, 272: 32401-32410 (1997).

Crea et al., "Chemical Synthesis of Genes for Human Insulin," <u>Proc Natl Acad Sci USA</u>, 75: 5765 (1978).

Cunningham and Wells, "High-Resolution Epitope Mapping of hGH-Receptor Interactions by Alanine-Scanning Mutagenesis," <u>Science</u>, 244: 1081-1085 (1989).

Ferlazzo et al., "Human Dendritic Cells Activate Resting Natural Killer (NK) Cells and Are Recognized Via the NKp30 Receptor by Activated NK Cells," <u>J Exp Med</u>, 195: 343-351 (2002).

Henry et al., "Cloning, Structural Analysis and Mapping of the B30 and B7 Multigenic Families to the Major Histocompatibility Complex (MHC) and Other Chromosomal Regions," <u>Immunogenetics</u>, 46: 383-395 (1997).

Hoffman et al., "Efficient Gene Transfer into Human Hepatocytes by Baculovirus Vectors," Proc Natl Acad Sci USA, 92: 10099-10103 (1995).

Ichikawa et al., "Analysis of the Fine B Cell Specificity During the Chronic/Relapsing Course of a Multiple Sclerosis-Like Disease in Lewis Rats Injected with the Encephalitogenic Myelin Oligodendrocyte Glycoprotein Peptide 35-55," <u>J Immunol</u>, 157: 919-926 (1996).

Kerlero de Rosbo et al., "Chronic Relapsing Experimental Autoimmune Encephalomyelitis with a Delayed Onset and an Atypical Clinical Course, Induced in PL/J Mice by Myelin Oligodendrocyte Glycoprotein (MOG)-Derived Peptide: Preliminary Analysis of MOG T Cell Epitopes," <u>Eur J Immunol</u>, 25: 985-993 (1995).

Lenschow et al., "CD28/B7 System of T Cell Costimulation," Annu Rev Immunol, 14: 233-258 (1996).

Leung et al., "A Method for Random Mutagenesis of A Defined DNA Segment Using A Modified Polymerase Chain Reaction," <u>Technique</u>, 1: 11-15 (1989).

Linsley et al., "Extending the B7 (CD80) Gene Family," <u>Protein Science</u>, 3: 1341-1343 (1994).

Madzak et al., "Efficient in Vivo Encapsidation of a Shuttle Vector into Pseudo-Simian Virus 40 Virions Using a Shuttle Virus as Helper," <u>J Gen Virol</u>, 73: 1533-36 (1992).

Margolskee, "Epstein-Barr Virus Based Expression Vectors," <u>Curr Top Microbiol</u> Immunol, 158: 67-93 (1992).

Mendel et al., "A Myelin Oligodendrocyte Glycoprotein Peptide Induces Typical Chronic Experimental Autoimmune Encephalomyelitis in H-2<sup>b</sup> Mice: Fine Specificity and T Cell Receptor Vβ Expression of Encephalitogenic T Cells," <u>J Immunol</u>, 25: 1951-1959 (1995).

Miller, "Retroviral Vectors," Curr Top Microbiol Immunol, 158: 1-24 (1992).

Miller, "Human Gene Therapy Comes of Age," Nature, 357: 455-460 (1992).

Moretta et al., "What is a Natural Killer Cell?" Nature Immunol, 3: 6-8 (2002).

Moss et al., "Poxvirus Expression Vectors," <u>Curr Top Microbiol Immunol</u>, 158: 25-38 (1992).

Muzyczka, "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells," <u>Curr Top Microbiol Immunol</u>, 158: 97-123 (1992).

Myers et al., "A General Method for Saturation Mutagenesis of Cloned DNA Fragments," Science, 229: 242-247 (1985).

Nalabolu et al., "Genes in a 220-kb Region Spanning the TNF Cluster in Human MHC," Genomics, 31: 215-222 (1996).

Nalabolu et al., "Human 1C7 precursor mRNA, alternatively spliced," EMBL Sequence Database, Accession No. AF031136. (1997)

Nalabolu et al., "Human 1C7 precursor mRNA, alternatively spliced," EMBL Sequence Database, Accession No. AF031137, (1997)

Nalabolu et al., "Human 1C7 precursor mRNA, alternatively spliced," EMBL Sequence Database, Accession No. AF031138. (1997)

Oaks et al., "Nucleotide Sequence of the ACI Rat CTLA-4 Molecule", Immunogenetics," 43: 173-174, (1996).

Pende et al., "Identification and Molecular Characterization of NKp30, a Novel Triggering Receptor Involved in Natural Cytotoxicity Mediated by Human Natural Killer Cells," J Exp Med, 190: 1505-1516 (1999).

Queen et al, "A Humanized Antibody that Binds to the Interleukin 2 Receptor," <u>Proc Natl Acad Sci USA</u>, 86: 10029-10033 (1989).

Stein et al., "Oligodeoxynucleotides as Inhibitors of Gene Expression: A Review," Cancer Res, 48: 2659-2668 (1998).

Strausberg. "Human cDNA clone IMAGE: 685808," EMBL Sequence Database, Accession No. AA262074 (1997).

Van Der Krol et al., "Modulation of Eukaryotic Gene Expression by Complementary RNA or DNA Sequences," <u>Biotechniques</u>, 6: 958-976 (1998).

Wells et al., "Cassette Mutagenesis: An Efficient Method for Generation of Multiple Mutations at Defined Sites," Gene, 34: 315-323 (1985).

Winter and Milstein, "Man-Made Antibodies," Nature, 349: 293-299 (1991).

Wolff et al., "Direct Gene Transfer into Mouse Muscle In Vivo," Science, 247: 1465-1468 (1990).

Pursuant to 37 C.F.R. 1.98(d), copies of the references cited above with an asterisk are not enclosed herewith, as they were previously cited by or submitted to the US Patent Office in United States patent application 09/560,855, filed April 28, 2000, from which the present application claims priority under 35 U.S.C. §120.

Applicant requests that these documents: (1) be fully considered by the Examiner during examination of this application and (2) be printed on any patent that may issue from this application. Applicant also requests that a copy of Form PTO-1449, as considered and initialed by the Examiner, be returned with the next communication.

An early and favorable action is respectfully requested.

Respectfully submitted,

James F. Haley, Jr. (Reg. No. 27,794)

Margaret A. Pierri (Reg. No. 30,709)

Attorneys for Applicant

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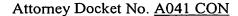
**Commissioner for Patents** 

P.O. Box 1450

Alexandria, VA 22313-1450 on

Claire J. Saniisan Goodman

Signature of Person Signing





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New York, New York September 30, 2004

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# TRANSMITTAL LETTER

Sir:

Transmitted herewith is: [X] an Information Disclosure Statement (in duplicate); [X] Form PTO-1449 (in duplicate); and [X] copies of cited references to be filed in the above-identified patent application.

The enclosed Information Disclosure Statement is being submitted more than three months from the application filing date but before the mailing date of the first Office Action on the merits.

In accordance with 37 C.F.R. § 1.97(b)(3), applicant believes that submission of this Information Disclosure Statement requires no fee. However, if for any reason a fee

is due, the Director is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075.

A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,

James F. Habey, Jr. (Reg. No. 27,794) Margaret A. Pierri (Reg. No. 30,709)

Attorneys for Applicant

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Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450 on

Claire J. Saint van Goodman

Signature of Person Signing

# **FORM PTO-1449**

# U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTY. DOCKET NO. A041CON	<b>APPLN. NO.</b> 10/696,259
APPLICANT	<b>CONF. NO.</b>
Jeffrey Browning	7052
FILING DATE	GROUP ART UNIT
October 28, 2003	1632

# U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,816,567	03/1989	Cabilly et al	530	387	
	5,176,996	01/1993	Hogan et al.	435	6	
	5,256,775	10/1993	Froehler	536	25.6	
	5,264,564	11/1993	Matteucci	536	23.1	

### **FOREIGN PATENT DOCUMENTS**

EXAMINER	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
INITIAL	DOCOMIEM I MOMBER	DATE	COUNTRY			YES	NO
	WO 95/06727	03/1995	PCT Int'l Appln.				
•	EP 0412762 A2	02/1991	Europe				
	EP 0750039 A1	12/1996	Europe				
•	EP 0031080 B1	07/1981	Europe				

# OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
	Adelman et al., "In Vitro Deletional Mutagenesis for Bacterial Production of the 20,000-Dalton Form of Human Pituitary Growth Hormone," <u>DNA</u> , 2: 183 (1983).
	Arulanandam et al., "A Soluble Multimeric Recombinant CD2 Protein Identifies CD48 as a Low Affinity Ligand for Human CD2: Divergence of CD2 Ligands during the Evolution of Humans and Mice," <u>J Exp Med</u> , 177: 1439-1450 (1993).
	Berkner et al., "Expression of Heterologous Sequences in Adenoviral Vectors," <u>Curr Top Microbiol Immunol</u> , 158: 39-61 (1992).
	Bandyopadhyay et al., "Expression of Complete Chicken Thymidine Kinase Gene Inserted in a Retrovirus Vector," Mol Cell Biol, 4: 749-754 (1984).
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	Burger, "Human Myelin/Oligodendrocyte Glycoprotein: A New Member or the L2HNK-1 Family," J. Neurochem, 61, 1822-1827 (1993).

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### **DATE CONSIDERED**

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. A041CON	APPLN. NO. 10/696,259 CONF. NO. 7052	
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT Jeffrey Browning		
	STATEMENT BY AFFEIGANT	FILING DATE October 28, 2003	GROUP ART UNIT 1632	
	heportiche et al., "TWEAK, a New Secreted Li kly Induces Apoptosis," <u>J Biol Chem,</u> 272: 324		actor Family that	
Crea (1978	et al., "Chemical Synthesis of Genes for Hum 8).	nan Insulin," Proc Natl Acad S	<u>sci USA,</u> 75: 5765	
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Marg (199	olskee, "Epstein-Barr Virus Based Expression 2).	n Vectors," <u>Curr Top Microbio</u>	l Immunol, 158: 67-93	
Auto		protein Peptide Induces Typical Chronic Experimenta ne Specificity and T Cell Receptor $V\beta$ Expression of -1959 (1995).		
Mille	r, "Retroviral Vectors," Curr Top Microbiol Imn	nunol, 158: 1-24 (1992).		
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More	etta et al., "What is a Natural Killer Cell?" <u>Natu</u>	re Immunol, 3: 6-8 (2002).		
Moss	s et al., "Poxvirus Expression Vectors," <u>Curr T</u>	op Microbiol Immunol, 158: 2	5-38 (1992).	

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	s et al., "A General Method for Saturation Mu 447 (1985).	tagenesis of Cloned DNA Fr	ragments," <u>Science,</u> 229:
	oolu et al., "Genes in a 220-kb Region Spann 22 (1996).	ing the TNF Cluster in Huma	an MHC," <u>Genomics</u> , 31:
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	oolu et al., "Human 1C7 precursor mRNA, altossion No. AF031138. (1997).	ernatively spliced," EMBL Se	equence Database,
Oaks (1996	et al., "Nucleotide Sequence of the ACI Rates).	CTLA-4 Molecule", Immunoo	genetics," 43: 173-174,
	e et al., "Identification and Molecular Charact red in Natural Cytotoxicity Mediated by Huma ).		
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	et al., "Oligodeoxynucleotides as Inhibitors o 2668 (1998).	f Gene Expression: A Revie	w," <u>Cancer Res</u> , 48:
	sberg. "Human cDNA clone IMAGE: 685808, 2074 (1997).	" EMBL Sequence Database	e, Accession No.
	Der Krol et al., "Modulation of Eukaryotic Gen ences," <u>Biotechniques</u> , 6: 958-976 (1998).	e Expression by Compleme	ntary RNA or DNA
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